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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,066	05/29/2001	Thomas R. Fuerst	4600-0293.20	7789

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EXAMINER

WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/769,066

Applicant(s)

FUERST ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claim 18 was amended in Paper No. 10 filed 20 June 2003. Claims 11-14 and 18 remain pending and under examination.

Rejection withdrawn

The rejection of claim 18 under 35 USC 112, second paragraph, is withdrawn in view of Applicant's amendment to the claim to depend from claim 12.

Rejections maintained

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-14 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Claims 11, 12, and 13 are unclear in reciting "encoding a polypeptide derived from the carboxy-terminal 549 amino acids of HEV reading frame 2" since it is not clear what modifications can be made to the nucleic acid sequence that encodes the carboxy-terminal 549 amino acids of HEV reading frame 2 and still fall within the claim limitations. While the specification at page 7 mentions that the polypeptide may have amino acids deleted from the carboxy terminus of the 549 amino acid polypeptide, e.g., it does not disclose what other modifications (deletions, additions, substitutions) fall within the limitation intended by "derived."

Applicant has pointed out that inventors may act as their own lexicographers and has pointed to the "Definitions" provided in the specification at page 16, lines 17-21, and page 14, line 1 - page 15, line 23, as providing sufficient definition for "derived from."

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Applicant's remarks in light of the cited portions of the specification have been considered but not found persuasive. The definitions for "derived from" in the specification as cited are definitions for polynucleotides "derived from" HEV; such polynucleotides have "the same or substantially the same basepair sequence as a region of an HEV genome, cDNA of HEV or complements thereof," or "display(s) homology as noted under "B" or "C" ...". Similarly, the discussion of "Sequence homology" is largely directed toward homology of polynucleotide sequences and does not provide a definition for a polynucleotide encoding "a polypeptide derived from the carboxy-terminal 549 amino acids of HEV open reading frame (ORF) 2." The definitions cited by Applicant define "derived from" in the context of polynucleotide sequences, while the claims recite "derived from" in the context of a polypeptide sequence. It remains unclear what type of and/or how many changes can be made to the carboxy-terminal 549 amino acids of HEV ORF 2 and still fall within the intended scope of the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-14 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a substantially isolated nucleic acid molecule encoding a polypeptide consisting of the carboxy terminal 549 amino acids of HEV open reading frame 2, does not reasonably provide enablement for a substantially isolated

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nucleic acid molecule encoding a polypeptide derived from the carboxy terminal 549 amino acids of HEV open reading frame 2, for reasons of record.

Applicant has argued that since it is clear from the sequences provided and the explanation of the meaning of "derived from" what nucleic acid sequences are covered by the claim, one of skill in the art could readily produce any of the nucleic acid sequences using well-known methods, including the recombinant methods disclosed, and test them for the required homology, thus teaching "how to make" the invention as required; and that any species that meet the homology requirements are operative species, thus meeting the "how to use" requirement under 35 USC 112, first paragraph.

These arguments have been considered but not found persuasive. The claims recite "derived from" in the context of the carboxy-terminal 549 amino acids of HEV ORF 2. The specification does not clearly provide a definition of the polynucleotides that encode such "derived from" polypeptides, and does not provide guidance as to how to make such polypeptides in terms that reasonably correspond in scope with the invention as claimed. Applicant's argument with respect to "how to use" is not understood, since it is not apparent that homology is a utility.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11-14 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,514,690 to Li et al., of record. Li et al. disclose nucleic acid sequences that encode HEV ORF 2 polypeptides derived from the C-terminal 549 amino acids of HEV ORF 2. In particular, Li et al. disclose nucleic acids encoding an HEV ORF 2 polypeptide consisting of amino acids 394-660, as well as nucleic acids encoding portions of the HEV ORF 2 referred to as 2.0, 2.1, and 2.2 (see claim 1, Fig. 5 and Fig. 6, e.g.), which are not seen to be any different from the claimed nucleic acids which are interpreted as reading on any nucleic acid sequence that falls within the nucleic acid sequence that encodes the C-terminal 549 amino acids of HEV ORF 2. US Patent No. 6,514,690 issued from a continuation-in-part of application 08/617927, filed September 24, 1994, which disclosed the subject matter relied upon in this rejection. The instant claims receive the benefit of the filing date of parent application 08/327952, viz. October 24, 1994.

Applicant has argued that the instant application claims priority to 08/240049, filed May 9, 1994, which issued as US Patent 5,686,239, which identifies the C-terminal

region of the second ORF, and discloses the full length nucleotide ORF2 sequence which includes the 549 C-terminus.

This argument has been considered but not found persuasive, since the instant claims recite features that do not find support in the 08/240049; the claims therefore do not enjoy the benefit of the filing date of 08/240049. For example, the 08/240049 does not disclose or make reference to the carboxy-terminal 549 amino acids of HEV ORF 2, or to a substantially isolated nucleic acid sequence encoding a polypeptide derived from the carboxy-terminal particular region of HEV ORF 2. The rejection is maintained.

Allowable subject matter

Claims limited to the recitation of a substantially isolated nucleic acid molecule encoding a polypeptide consisting of the carboxy terminal 549 amino acids of HEV open reading frame 2, and/or a substantially isolated nucleic acid molecule consisting of SEQ ID NO:3 or SEQ ID NO:4 would be allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
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dcw